STATE OF MICHIGAN
IN THE MICHIGAN SUPREME COURT

(On Appeal from the Michigan Court of Appeals and the Circuit Court for the County of Eaton)

TERI WALTERS and KIM WALTERS

Plaintiffs-Appellees,

v

DONALD S. FALIK d/b/a FALIK FAMILY DENTISTRY; DONALD S. FALIK, D.D.S.; ROBERT C. FALIK, D.D.S. and JANE DOE, jointly and severally

Defendants-Appellants.

_____/

Sup. Ct. No. _____
COA No. 319016
Trial Court No: 12-658-NH

DEFENDANTS-APPELLANTS' APPLICATION FOR LEAVE TO APPEAL (AFTER REMAND)

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STATEMENT OF ORDER APPEALED FROM AND NEED FOR SUPREME COURT REVIEW

This is the second time Defendants- Appellants have filed an Application for Leave to Appeal with the Michigan Supreme Court. Defendants-Appellants Donald S. Falik D/B/A Falik Family Dentistry; Donald S. Falik, D.D.S.; Robert C. Falik, D.D.S. and Jane Doe ("Defendants"), seek either leave to appeal or peremptory reversal of a 2-1 per curiam opinion of the Michigan Court of Appeals dated August 16, 2016, which, on remand from the Supreme Court, reversed for the second time the trial court's order dated October 2, 2013, striking Plaintiffs' medical causation expert after finding that his opinion was not scientifically reliable. **(see: Exhibits H and E). Over the dissent of Court of Appeals Judge P. Meter, the majority opinion of the Court of Appeals has now held on two occasions that the Plaintiff's expert's opinion was scientifically reliable notwithstanding the absence of scientific data, testing or literature supporting that opinion and implicitly that the trial court's ruling to the contrary was an abuse of discretion (Exhibit H, JJ. Murphy and Servitto).**

This action arose after Plaintiff suffered an unintended exposure to phosphoric acid contained in a dental etching solution inadvertently supplied to her by Defendants during dental treatment. Plaintiffs allege that that use of the etching solution caused her a rare form of "vasculitis" (destruction of blood vessels caused by inflammation) known as Wegener's Granulomatosis (hereinafter "Wegners" or "WG").

At issue is whether the trial court acted within the proper exercise of its discretion in striking the testimony of Plaintiff's medical causation expert under MRE 702 and MCL 600.2955 after the court closely scrutinized the substance and scientific basis of the opinion

and found the opinion to be unsupported by any reliable scientific data, principles or methods. **In particular, the trial court had been presented with an undisputed record substantiating the complete absence of any scientific data, testing or literature associating exposure to phosphoric acid and the onset of WG. The Court of Appeals' majority opinion reversed on two separate occasions.**

In its first opinion, dated January 29, 2015, a majority of the Court of Appeals panel found the expert opinion to be scientifically reliable by utilizing the Sir Bradford Hill - criteria of causation.

This initial Court of Appeals opinion was vacated by an Order of the Michigan Supreme Court dated April 25, 2016. In that order, the Supreme Court also remanded the action to the Court of Appeals for reconsideration in light of a new opinion issued by the Supreme Court, in *Elher v Misra*, 499 Mich 11; 878 NW 2d 790 (2016). (Supreme Court Order, 4-25-16, attached hereto as Exhibit G).

Following supplemental briefing by the parties, the Court of Appeals issued its second set of written Opinions on August 16, 2016 **(See: Exhibit H)**. The majority opinion again vacated the trial court's order and held that *Elher* supported a ruling that the Plaintiff's expert opinion was scientifically valid notwithstanding the absence any scientific data, testing or literature associating exposure to phosphoric acid and the onset of WG. Without doing so expressly, the Court of Appeals majority essentially re-applied the Sir Bradford Hill criteria of causation and applied analogies to scientific acceptance of a causational link between exposure to pesticides containing phosphates and the onset of WG.

The major issue of significance to the jurisprudence of the state is whether—absent evidence of scientific data, testing or literature -- the Sir Bradford Hill criteria

of causation may be used as a substitute for the other controlling criteria of scientific reliability set forth by the Michigan Supreme Court and Michigan legislature where the controlling statute does not authorize the substitution and where, in other jurisdictions, the Sir Bradford Hill criteria may not be used as an appropriate methodology by an epidemiologist to establish medical causation unless there is first a showing of the existence of independent data from controlled studies demonstrating an association between the subject agent and the medical condition. See, e.g. *In re Fosamax Prods Liab Litigation, infra*, 645 F Supp 2d 164, 188 (SD NY 2009). No such threshold showing was made in the trial court, as articulated by both the trial court and the Court of Appeals' dissenting opinion.

In this regard, the Court of Appeals' majority opinion constitutes a ruling of first impression and is completely contrary to all the published case-law in any jurisdiction. Otherwise, as also articulated by the Court of Appeals' initial dissenting opinion, the majority opinion is palpably erroneous because it did not give the appropriate deference to the trial court's findings under the "abuse of discretion" standard of review.

Simply put, the Court of Appeals majority overreached its authority in clear violation of the controlling standards. The Supreme Court is requested to vacate the Court of Appeals' majority Opinion and reinstate the trial court's ruling for the reasons set forth in the Court of Appeals' initial dissenting Opinion.

STATEMENT OF ISSUE

DID THE CIRCUIT COURT ACT WITHIN THE PROPER EXERCISE OF ITS DISCRETION IN STRIKING THE TESTIMONY OF PLAINTIFFS' MEDICAL CAUSATION EXPERT UNDER MRE 702 and MCL 600.2955 WHERE THE COURT CLOSELY SCRUTINIZED THE SUBSTANCE AND SCIENTIFIC BASIS OF THE EXPERT OPINION AND FOUND THE OPINION TO BE UNSUPPORTED BY ANY RELIABLE SCIENTIFIC PRINCIPLES OR METHODS - - INCLUDING THE COMPLETE ABSENCE OF A RECOGNIZED ASSOCIATION BETWEEN PHOSPHORIC ACID AND WG?

The Circuit Court said: Yes

The Court of Appeals said: No

Plaintiffs-Appellees say: No

Defendants-Appellants say: Yes

STATEMENT OF FACTS

This is an ordinary negligence and malpractice action arising out of dental care Plaintiff Teri Walters ("Plaintiff") received from the Falik Family Dentistry dental office. In their pleadings in the trial court, Plaintiffs allege that Defendants' receptionist erroneously provided Plaintiff Terri Walters ("Plaintiff") with dental etching solution rather than teeth whitening solution. The etching solution is composed of 35% phosphoric acid according to its package insert. In addition to claiming some damage to the enamel of Plaintiff Teri Walter's teeth, Plaintiffs have further alleged that use of the etching solution also caused her a rare form of "vasculitis" (destruction of blood vessels caused by inflammation) known as Wegener's Granulomatosis (hereinafter "Wegeners" or "WG").

Over the years, not much has become known about this disease and no one knows what causes it to this day. However, parts of the medical community have postulated that the condition may be a combined sum of a person's genetic make-up and one or more internal or external/environmental component. The most hypothesized environmental contributor is a bacteria known as Staph Aureus. There are also limited studies that have theorized a correlation between silica dust and perhaps farming and Wegener's. **It is undisputed -- and the Court of Appeals' majority opinion finally acknowledged below -- that there is no scientific data, scientific study, or any peer-reviewed articles by any member of the medical community anywhere that has associated etching solution or phosphoric acid with Wegener's Granulomatosis.**

Plaintiffs retained rheumatologist Dr. M. Eric Gershwin as a causation expert to support their claim that the Plaintiff Teri Walter's WG was proximately caused by her use of the dental etching solution. Dr. Gershwin's qualifications are not at issue in this appeal. The reliability of

his opinion is however at issue.

Dr. Gershwin testified at this deposition that studies have shown that the condition, or at least an acute flare up, is caused by a combination of genetic influences and some environmental component in combination. Dr. Gershwin identified those environmental components as silica, farming, pesticides, bacterial infections and hydrocarbons (Gershwin dep., pp 21-26, attached hereto as **Exhibit B**). He admitted that he has never known of a case where etching solution or phosphoric acid caused Wegener's. Nor was he aware of any literature in which such a conclusion is documented (*id*., pp 21-25). Due to the uniqueness of his theory herein, he wishes to use Plaintiff as a test-case for publication (*id*., p 22).

When asked about whether there exist any studies or other data regarding a link between phosphoric acid or dental etching solution to Wegener's, Dr. Gershwin simply deflected the questions and mocked defense counsel. A key example question and condescending response is:

> Q. Do any of the literature pieces that you provided conclude that phosphoric acid causes or contributes to Wegener's?
>
> A. Well, again, the use of your words, the exact choice of your words would be no. But on the other hand, there is data about solvents, hydrocarbons, and agriculture. And I remind people that phosphorous and the element Si, silica, are adjacent to each other in the table of different chemicals. Remember what the periodic table is? . . .

(**Exhibit B**, p 22).

Gershwin testified that WG occurs in persons who are genetically predisposed to having a "promiscuous" immune system that is highly responsive to antibodies. He stated that some mechanism will induce the death of cells, causing the release of a "neutrophillic antigen." (*Id*., pp 16-17, 33). He explained that a person who is genetically susceptible will then mount an immune response.

Gershwin testified that what happened to Plaintiff was that the phosphoric acid hit water, dissociated, and produced a large inflammatory and immune response. He opined that although plaintiff might have gotten WG at some point regardless, she would not have gotten it when she did without the exposure to the etching solution (*id*., p 33).

Defendants filed a motion in limine to exclude Dr. Gershwin's testimony due to lack of reliability of his opinion and supporting evidence that exposure to phosphoric acid is recognized in the medical community as a cause of WG. In further support of Defendants' position, Defendant attached an affidavit of Ms. Walters' own treating rheumatologist, Dr. Monika Mohan. She not only opines that the etching solution did not cause the Wegener's, but she has also expressly informed Mrs. Walters that it did not. Dr. Mohan is also unaware of any literature in her profession that supports this theory offered by plaintiff's expert (see**: Exhibit C).**

The trial court heard arguments on the motion on September 19, 2013, and issued a detailed and highly reasoned decision from the bench.

Applying MRE 702, the court found that Gershwin was qualified in the field of rheumatology and that expert testimony would assist the trier of fact (Tr. 9-19-13, p 20, attached hereto as **Exhibit A**). However, it held that it was questionable whether his opinion was based on sufficient facts and reliable data, principals and methods (*id*., pp 20-21). The court found that the majority of the articles presented by the parties indicated that the etiology for WG was unknown, and none of the studies referred to phosphoric acid or any kind of acid exposure as a cause (*id*., pp 24, 29). The court believed that Dr. Gershwin's use of the phrase "environmental factors" to describe the source of causation of the disease was too "broad" to permit the analogies he made to phosphoric acid as the source here. (*id*., pp 21, 25, 28)

The trial court also noted that the literature did not support Gershwin's conclusions with the same degree of certainty that he described (*id.*, pp 26-27, 29-30). Observing Dr. Gershwin's desire to use Plaintiff as a case- study because she is the first case involving etching solution-phosphoric acid as the cause of WG, the court stated that "the cutting edge of medicine is simply not the standard for a courtroom. In applying MRE 702, I just don't find his testimony reliable enough to allow it to go to the jury. So I'm going to grant the motion" (*id.*, pp 31-32). A written order was entered October 2, 2013 (attached hereto as part of **Exhibit E**).

Plaintiffs' counsel questioned the court regarding the possibility of conducting a "Daubert" evidentiary hearing prior to implementation of its ruling (*id.*, p 32). The trial court informed Plaintiffs that it would indeed proceed with an evidentiary hearing, wherein the Plaintiffs would have the burden of demonstrating that Dr. Gershwin's opinions were properly admissible (*id.*, p 34). Plaintiffs however never followed up to schedule such a hearing. Rather, Plaintiffs filed a motion for reconsideration merely restating their prior arguments and attached additional articles. Plaintiff's motion for reconsideration was denied by Order dated October 22, 2013 (see: **Exhibit F**).

Initial Court of Appeals Proceedings

In a 2-1 decision dated January 29, 2015, upon leave granted, the Michigan Court of Appeals reversed (**Exhibit D**). The Court of Appeals majority (JJ Murphy and Servitto) applied the Sir Bradford Hill methodology of establishing medical causation to scientifically validate the expert opinion. In addition, the majority relied upon independent data purporting to "associate" other environmental agents, such as silica and fertilizer, to the disease. However, Court of Appeals Judge Meter dissented. He concluded, in pertinent part, that the Bradford Hill

criteria could not be used absent independent data demonstrating an "association" between phosphoric acid and WG.

Supreme Court Proceedings

Defendants filed an Application for Leave to Appeal with the Michigan Supreme Court. The Supreme Court vacated the Court of Appeals Opinion by an Order dated April 25, 2016. In that order, the Supreme Court also remanded the action to the Court of Appeals for reconsideration in light of a new opinion issued by the Supreme Court, in *Elher v Misra*, *supra*. (Supreme Court Order, 4-25-16, attached hereto as **Exhibit G**).

Remanded Court of Appeals Proceedings

Following supplemental briefing by the parties, the Court of Appeals issued its second set of written Opinions on August 16, 2016 **(See: Exhibit H)**. The majority opinion again vacated the trial court's order and held that *Elher* supported a ruling that the Plaintiff's expert opinion was scientifically valid notwithstanding the absence any scientific data, testing or literature associating exposure to phosphoric acid and the onset of WG (*id*., JJ Murphy and Servitto). Without doing so expressly, the Court of Appeals majority essentially re-applied the Sir Bradford Hill criteria of causation in the same manner as it did in its initial, vacated opinion and applied analogies by way of some scientific acceptance of a causational link between exposure to pesticides containing phosphates and the onset of WG (*Id*., pp. 13-15).

Court of Appeals Judge Meter again dissented for the reasons set forth in his initial dissenting opinion (*id*., J. Meter dissenting).

For the reasons set forth in Judge Meter's dissenting opinion, Defendants request affirmative relief from the Michigan Supreme Court.

STANDARD OF REVIEW

A trial court's decision to admit or exclude evidence is reviewed for an abuse of discretion. *Craig v Oakwood Hosp*, 471 Mich 67, 76, 684 NW2d 296 (2004). "An abuse of discretion occurs when the court chooses an outcome that falls outside the range of reasonable and principled outcomes," *Elher*, supra, 499 Mich at 20, or "when the result is so palpably and grossly violative of fact and logic that it evidences perversity of will or the exercise of passion or bias rather than the exercise of discretion." *Maldonado v Ford Motor Co*, 476 Mich 372, 388, 719 NW2d 809 (2006); *People v Unger*, 278 Mich App 210, 217, 749 NW2d 272 (2008); *Dacon v Transue*, 441 Mich 315, 329, 490 NW2d 369 (1992). On the issue of the proper exercise of the trial court's "gatekeeper function" *infra*, an abuse of discretion "occurs when the trial court chooses an outcome falling outside the range of principled outcomes." *Edry v Adelman*, 486 Mich 634, 639: 786 NW 2d 567 (2010).

The text of the Court of Appeals' majority opinion does not explicitly demonstrate that the majority weighed whether the trial court's ruling fell "outside the range of reasonable and principled outcomes," *Elher*, supra, or was "so palpably and grossly violative of fact and logic that it evidences perversity of will or the exercise of passion or bias rather than the exercise of discretion." *Maldonado v Ford Motor Co*, *supra*. Rather, the Court of Appeals majority opinion reads as if the panel erroneously conducted its own *de novo* balancing of factors.

ARGUMENT

THE CIRCUIT COURT ACTED WITHIN THE PROPER EXERCISE OF ITS DISCRETION IN STRIKING THE TESTIMONY OF PLAINTIFF'S MEDICAL CAUSATION EXPERT UNDER MCL600.2955(1) AND MRE 702 WHERE THE COURT CLOSELY SCRUTINIZED THE SUBSTANCE AND SCIENTIFIC BASIS OF THE OPINION AND FOUND THE OPINION TO BE UNSUPPORTED BY ANY RELIABLE SCIENTIFIC PRINCIPLES OR METHODS.

A. The Trial Court's Gatekeeper Function

To establish a claim for medical malpractice, a plaintiff must prove: (1) the applicable standard of care, (2) breach of that standard of care by the defendant, (3) injury, and (4) proximate causation between the alleged breach and the injury. *Woodard v Custer*, 473 Mich 1, 6; 702 NW2d 522 (2005). Generally, expert testimony is required in medical malpractice cases. *Id*. To satisfy the causation element, the plaintiff must show that but for the defendant's actions, the injury would not have occurred, and that the consequences of the defendant's actions were foreseeable. *Craig v Oakwood Hosp*, 471 Mich 67, 86-87, 684 NW2d 296 (2004). It is not sufficient for the plaintiff to show that the defendant may have caused the injuries; rather, she must set forth "specific facts that would support a reasonable inference of a logical sequence of cause and effect." *Id*. at 87. The plaintiff need not negate other possible causes of the injury, but the evidence must exclude other reasonable hypotheses with a fair amount of certainty. *Id*. at 87-88.

MRE 702 governs the admissibility of expert testimony and provides:

> If the court determines that scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The admissibility of scientific expert testimony is also governed by MCL 600.2955(1), (2), which provides:

> In an action for the death of a person or for injury to a person or property a scientific opinion rendered by an otherwise qualified expert is not admissible unless the court determines that the opinion is reliable and will assist the trier of fact. In making that determination, the court shall examine the opinion and the basis for the opinion, which basis includes the facts, technique, methodology, and reasoning relied on by the expert, and shall consider all of the following factors:
>
> (a) Whether the opinion and its basis have been subjected to scientific testing and replication.
> (b) Whether the opinion and its basis have been subjected to peer review publication.
> (c) The existence and maintenance of generally accepted standards governing the application and interpretation of a methodology or technique and whether the opinion and its basis are consistent with those standards.
> (d) The known or potential error rate of the opinion and its basis.
> (e) The degree to which the opinion and its basis are generally accepted within the relevant expert community. As used in this subdivision, "relevant expert community" means individuals who are knowledgeable in the field of study and are gainfully employed applying that knowledge on the free market.
> (f) Whether the basis for the opinion is reliable and whether experts in that field would rely on the same basis to reach the type of opinion being proffered.
> (g) Whether the opinion or methodology is relied upon by experts outside of the context of litigation.
> (2) A novel methodology or form of scientific evidence may be admitted into evidence only if its proponent establishes that it has achieved general scientific acceptance among impartial and disinterested experts in the field.
>
> MCL 600.2955(1), (2).

MRE 702 "requires trial judges to act as gatekeepers who must exclude unreliable expert testimony." Staff Comment to 2004 Amendment of MRE 702. In *Gilbert v Daimler Chrysler*, 470 Mich, 749, 782 (2004), the Supreme Court elaborated that the trial court's gatekeeper role:

> … applies to all stages of expert analysis. MRE 702 mandates a searching inquiry, not just of the data underlying expert testimony, but also of the manner in which the expert interprets and extrapolates from those data. Thus, it is

> insufficient for the proponent of expert opinion merely to show that the opinion rests on data viewed as legitimate in the context of a particular area of expertise (such as medicine). The proponent must also show that any opinion based on those data expresses conclusions reached through reliable principles and methodology.
>
> *Id.*, at 782.

Before admitting expert scientific testimony, the trial court must satisfy its "fundamental duty" of ensuring that the expert testimony is reliable and relevant. *Chapin v A & L Parts Inc*, 274 Mich App 122; 732 NW 2d 578 (2007). MRE 702 explicitly incorporates the federal- *Daubert* standards of admissibility regarding an expert's testimony. *Id*. This requires that the proponent of the testimony establish its reliability "by showing that it 'is based on sufficient facts or data,' that it 'is the product of reliable principles and methods,' and that the proposed expert witness 'has applied the principles and methods reliably to the facts of the case.'" *People v Unger*, 278 Mich App 210, 217; 749 NW2d 272 (2008), quoting MRE 702.

This analysis does not hinge on discovering "absolute truth," or resolving "genuine scientific disputes." *Chapin, supra*, 274 Mich App at 137. Rather, the trial court is tasked with filtering out unreliable expert evidence. "The inquiry is into whether the opinion is rationally derived from a sound foundation." *Chapin*, 274 Mich App at 139. "The standard focuses on the scientific validity of the expert's methods rather than on the correctness or soundness of the expert's particular proposed testimony." *Unger*, 278 Mich App at 217-218. An expert's testimony meets the *Daubert* standard of reliability when the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co, Ltd v Carmichael*, 526 US 137, 152; 119 S Ct 1167; 143 L Ed 2d 238 (1999). As the United States Supreme Court emphasized in *Daubert v Merrell Dow Pharmaceuticals*, 509 US 579 at 594-595 (1993):

> The inquiry envisioned by Rule 702 is . . . a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.
>
> *Id*.

Equally as significant, in *Gilbert*, the Michigan Supreme Court relied upon the United States Supreme Court's holding in *GE v Joiner*, 522 US 136, 118 S Ct 512, 139 L Ed 2d 508 (1997) for the proposition that a court may not overlook an 'analytical gap' between that data and the opinion expressed by an expert. In *Joiner*, the United States Supreme Court stated:

> Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.
>
> 522 US at 146.

The absence of supporting literature is an important factor in determining the admissibility of expert witness testimony. See *Craig*, 471 Mich. at 83-84, 684 N.W.2d 296 (stating that the expert's singular reliance on his own hypothetical depiction of an event may have been too speculative and, therefore, inadmissible under MRE 702), *Edry v Adelman*, 486 Mich 634, 640; 786 NW 2d 567 (2010). See, also, *Daubert*, 509 U.S. at 593 (stating that whether there is peer-reviewed and published literature on a theory is a "pertinent consideration" because "submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected").

Edry v Adelman, supra, is instructive, in determining the reliability of medical causation-expert testimony in a context similar to here.

In *Edry*, the Supreme Court reviewed a trial court's exclusion of causation testimony in a medical malpractice case arising from the delayed diagnosis of breast cancer. The challenged expert witness testified that the delay reduced the plaintiff's five-year survival chance to 20%. 486 Mich at 637. The expert maintained this position even after being confronted with authoritative data reflecting a 60% five-year survival rate, and failed to substantiate his view with any countervailing literature or data. Id. The Supreme Court upheld the exclusion of his testimony, holding that it "failed to meet the cornerstone requirements of MRE 702." *Id*. at 640. The Court reasoned, "Dr. Singer's opinion was not based on reliable principles or methods; his testimony was contradicted by both the defendant's oncology expert's opinion and the published literature on the subject that was admitted into evidence, which even Dr. Singer acknowledged as authoritative." ***Id.*** The testimony was deficient, the Court concluded, because it lacked "some basis in fact," as well as a foundation demonstrating that it drew upon reliable principles or methods, or that the witness had reliably applied his methods to the facts of the case. *Id*. at 641.

B. Summary of *Elher v Misra*

In *Elher,* the Plaintiff brought a medical malpractice action seeking damages after her surgeon accidentally clipped her common bile duct while performing a laparoscopic cholecystectomy. Plaintiff sought to admit expert testimony stating that clipping a patient's common bile duct during an otherwise uncomplicated laparoscopic cholecystectomy was a breach of the applicable standard of care.

Defendants in that action moved to exclude Plaintiff's proposed expert testimony on the ground that, because it was not supported by peer-reviewed literature or the opinions of other physicians, it did not meet the standards for reliability set forth in MRE 702 and MCL

600.2955. The Michigan Court of Appeals majority held in pertinent part that the Plaintiff's expert testimony was scientifically reliable and otherwise admissible. The majority excused the absence of peer reviewed literature and other scientific acceptance that supported the opinion of Plaintiff's expert. 499 Mich at 19-20. The Michigan Supreme Court reversed and struck the expert testimony as unreliable.

The Supreme Court majority re-emphasized that the proponent of expert testimony in a medical malpractice case must satisfy the court that each aspect of proposed expert testimony, including the underlying data and methodology, is scientifically reliable. *Elher* stated that MCL 600.2955 requires the trial court to determine whether the expert's opinion is reliable and will assist the trier of fact by examining the opinion and its basis, including the facts, technique, methodology, and reasoning relied on by the expert. *Id*., at 22-24.

Thus, the controlling question there was whether the expert's opinion (that absent scarring or inflammation, it is virtually always a breach of the standard of care to clip the common bile duct during a laparoscopic cholecystectomy) was sufficiently reliable under the standards articulated in MRE 702 and MCL 600.2955.

***Elher* explained that on appellate review, the focus must be on whether the trial court abused its discretion in balancing the enumerated factors for determining reliability listed in MCL 600.2955, which may not all be relevant in every case.** The Supreme Court concluded that the trial court in that case did not abuse its discretion by relying on two of the statutory factors: (1) whether the opinion and its basis had been subjected to peer reviewed publications and (2) the degree to which the opinion and its basis were generally accepted within the relevant expert community. *Id*., pp 25-26.

As applied to the facts of that case, the Supreme Court in *Elher* explained that, contrary to the Court of Appeals majority's opinion therein, Defendants there presented evidence that there was peer-reviewed medical literature suggesting that most bile duct injuries occur because of misperception and that such misperception errors do not constitute negligence. The Supreme Court observed that, critically, while the issue had been studied in peer reviewed literature, the plaintiff failed to submit any peer-reviewed medical literature supporting her expert's opinion. *Id*., pp 26-27.

Second, although some evidence was presented indicating that some physicians agreed with plaintiff's expert, there was no evidence regarding the degree to which his opinion was generally accepted in the relevant expert community. On the other hand, the Supreme Court held that the trial court abused its discretion by relying on the fact that the opinion of plaintiff's expert had not been subjected to scientific testing or replication because that statutory factor was not relevant to the type of opinion at issue. However, that error did not render the trial court's ultimate exclusion of the expert testimony under MCL 600.2955 an abuse of discretion given that, to establish the scientific reliability of the expert opinion, plaintiff relied solely on her expert's background and experience, factors that by themselves are generally insufficient to support a finding of reliability (*id*.).

Elher also held that the trial court did not abuse its discretion by concluding that the proposed testimony of plaintiff's expert was deficient because it did not meet the requirements of MRE 702. The opinion of plaintiff's expert was not based on reliable principles or methods, his opinion was contradicted by the opinion of defendant's expert and published literature on the subject that was admitted into evidence, and there was no literature supporting the testimony of plaintiff's expert admitted into evidence. The Supreme Court concluded that while

peer-reviewed, published literature is not always necessary or sufficient to meet the requirements of MRE 702, the absence of supporting literature and of any other form of reliable support rendered the opinion of plaintiff's expert unreliable and inadmissible under MRE 702 *Id*., at 27.

C. Import of *Elher* Upon This Action

Prior to being vacated by the Supreme Court, the Court of Appeals' original majority opinion in this action reversed the trial court by utilizing the "Sir Bradford Hill" - criteria of causation to scientifically validate the expert opinion under MRE 702 and MCL 600.2955 – even absent the support of scientific data, testing or literature. On remand, the Court of Appeals conducted the same analysis (while omitting express mention of Sir Bradford Hill) as a remaining viable analysis even after *Elher*. Defendants contend that this was erroneous because the Sir Bradford Hill criteria of substantively establishing causation do not serve as a substitute for the statutory criteria used in Michigan as a threshold basis to scientifically validate an expert opinion for purposes of admissibility. Moreover, *Elher* further illustrates the mandatory nature of utilizing the statutory criteria in this regard—under which there is no room to substitute a substantive alternative of establishing causation for the threshold "reliability" analysis for admissibility purposes.

Instead, the common thread between *Elher* and the instant action was the conclusion in *Elher* that the trial court in that case did not abuse its discretion by relying on two of the statutory factors: (1) whether the opinion and its basis had been subjected to peer reviewed publications and (2) the degree to which the opinion and its basis were generally accepted within the relevant expert community *Id*., pp 25-26. The trial court

below relied upon the same two factors and the same two considerations control a finding that the trial court did not abuse its discretion in doing so.

D. Elher Does Not Support the Substitution of The Sir Bradford Hill Method of Determining Causation For the Required Reliability Analysis

Epidemiology is the scientific field and primary generally accepted methodology concerned with identifying a causal nexus between external (e.g., chemical) risk factors and the onset of a disease or medical condition. *Nelson v American Sterilizer Co*. 223 Mich App 485, 492-493; 566 NW 2d 671 (1997), *DiGuidio v Centocor Ortho Biotech, Inc*., 3 F Supp 3d 674 (WD Ohio, 2014). It is observational research that focuses upon the differences between those that have had a particular exposure and those that have not. 223 Mich App at 493.

In federal courts and other jurisdictions, the Bradford Hill criteria is a method for determining whether the results of an epidemiological study can be said to demonstrate causation and is not a method for testing an unproven hypothesis. See, e.g. *DiGuidio, supra,* 3 F Supp 2d at 678, *Dunn v Sandoz Pharms. Corp,* 275 F Supp 2d 672, 677 (MD N Car 2003). In the instant action, the Court of Appeals majority approved Dr. Gershwin's use of this set of criteria (with a needed analogy to pesticides) to establish the reliability of his hypothesis regarding medical causation, and reversed the trial court's refusal to do so without examining the trial court's ruling under the abuse of discretion standard.

The mandatory starting point of the Sir Bradford Hill criteria is as an association between two variables that is "perfectly clear-cut and beyond what we would care to attribute to the play of chance." *Dunn*, supra, at 677, quoting Bradford Hill, The Environment and Disease: Association or Causation, 58 Proc. Royal Soc y Med. 295, 295-300 (1965). Accord: *Harris v*

CSX Transportation, 753 NE 2d 275, 290-291 (W Va 2013*), Tomlinson v Advanced Micro devices, Inc*., 81 A. 3d 1264, 1272 (Del 2013).

Indeed, "several courts that have considered the question have held that it is not a proper methodology for an epidemiologist to apply the Bradford Hill factors without data from controlled studies showing an association." *In re Fosamax Prods Liab Litigation*, 645 F Supp 2d 164, 188 (SD NY 2009). See also *Amorc1ianos v National Railroad Passenger Corp*, 137 F Supp 2d 147 (ED NY 2001) ["Even when an appropriately designed study yields evidence of a statistical association between a given substance and a given health outcome, epidemiologists generally do not accept such an association by itself as proof of a causal relationship between the exposure and the outcome. Epidemiologists generally look to several additional criteria to determine whether a statistical association is indeed causal."] (internal citations omitted); *In re Breast Implant Litigation*, 11 F Supp 2d 1217, 1234 n 5 (D Colo 1998) [The Bradford-Hill criteria start with an association demonstrated by epidemiology and then apply such criteria as the temporal sequence of events, the strength of the association, the consistency of the observed association, the dose-response relationship, and the biologic plausibility of the observed association.]

The Federal Judicial Center's Manual on Scientific Evidence also contains a description of the Bradford Hill criteria. *Dunn, supra*, citing *Reference Manual on Scientific Evidence* 336-37 (2d ed. 2000). The first step in the causation analysis pursuant to Bradford Hill is an epidemiological study that has identified an association between two variables. Once a study has shown that there is an association, the next step is to determine whether the "association identified in an epidemiologic study may or not be causal." *Id*. The toxicology section of the

Manual does not include the Bradford Hill criteria as a method for determining causation between a drug and disease. *Dunn, supra*.

In this context, the term "association" is a term of art in epidemiology. It has been defined as "[t]he degree of statistical dependence between two or more events or variables." *In re TMI Litig*, 193 F3d 613, 710 n159 (3d Cir 1999) [internal quotations and citation omitted]. Moreover, an association is not the same as causation. An epidemiological association identified in a study may or may not be causal. "Although epidemiological studies cannot prove causation, they do provide a basis for an epidemiologist to infer that a chemical agent can cause a disease." Syl. pt. 7, *King v Burlington Northern Santa Fe Ry Co.*, 762 NW2d 24, 28 (Neb 2009). "Assessing whether an association is causal requires an understanding of the strengths and weaknesses of the study's design and implementation, as well as a judgment about how the study findings fit with other scientific knowledge." Michael D. Green et al., *Reference Guide on Epidemiology, in* Reference Manual on Scientific Evidence 549, 553 (3d ed. 2011). Accord: *Harris v CSX Transportation*, 753 SE 2d 275 (W. Va. 2013).

The Michigan Supreme Court nor the legislature have yet to recognize the validity of the Sir Bradford Hill criteria of causation in Michigan, especially absent scientific studies supporting the association between a specific agent and the subject disease. However, in *Chapin v A & L Parts, Inc*., 274 Mich App, 122, 135; 732 NW 2d 538 (2007), the Michigan Court of Appeals accepted an expert's reliance upon the "Sir Bradford Hill" methodology for determining causation between exposure to asbestos by automobile brake workers and the disease of mesothelioma where the link between asbestos exposure and the disease was undisputed within the scientific community:

> The Sir Bradford Hill methodology, as explained by Dr. Lemen, contains nine criteria, all of which should be considered when determining causation. "Strength of association" means a sufficiently strong association between a substance and an effect can permit conclusions without statistical epidemiologic data. For example, no epidemiological studies were needed to show that cyanide gas kills film-recovery plant workers when they are exposed to it. Dr. Lemen explained that epidemiological evidence "is clearly the best that we've got" and "it leaves little doubt" when it exists, but it was not needed to draw conclusions on which to base preventive actions. "Temporality" means that cause must precede effect or there can be no association. "Biologic gradient," or "response gradient," refers to basic toxicological knowledge that more exposure increases the risk of disease, as asbestos does. "Consistency" means a given effect must "be observed repeatedly in multiple studies," preferably different kinds of studies, and "specificity" means an agent always causes the same kind or kinds of disease. It is undisputed that asbestos consistently causes the same few diseases. "Biological plausibility" looks at whether a theory of causation comports with other known facts, such as whether an agent can actually affect a certain body part, and asbestos fits this criterion. "Coherence" is similar to biological plausibility in that it checks for inconsistency with other theories of causation. Dr. Lemen noted that the animal studies and the biological studies on asbestos fit together. "Experimental evidence" could include animal and laboratory studies in the case of asbestos, and the experimental evidence also connected asbestos to the same diseases. It would, of course, be unethical to perform clinical experiments on people by deliberately exposing them to asbestos to confirm its toxicity, no matter how probative such an experiment might be.
>
> The final factor in the Sir Bradford Hill methodology is "analogy." Dr. Lemen explained that, as applied to the circumstances of this case, "analogy" looks at whether automobile brake workers are actually exposed to enough of the agent under discussion to cause disease. Dr. Lemen again stated that there was no known safe exposure level to asbestos below which it would not cause mesothelioma, and studies exist showing that automobile brake workers are exposed to asbestos, thereby indicating a cause and effect relationship. On the basis of all of the foregoing factors, combined with the known asbestos exposure and "thousands of epidemiological studies and animal studies and toxicological studies," Dr. Lemen concluded that there was ample scientific evidence to link mesothelioma to occupational exposure to asbestos-containing brake products. Dr. Lemen further pointed out that none of the factors was dispositive by itself, but the best way to determine causation was to consider them all and to further consider reports issued by governments and health agencies or organizations.
>
> 274 Mich App at 133-135.

Within all these authorities, the overriding principle is simple: [t]he Bradford Hill criteria is a method for determining whether the results of an epidemiological study can

be said to demonstrate causation and not a method for testing an unproven hypothesis." 275 F. Supp 2d at 677.

E. The Trial Court Acted Within Its Proper Exercise Of Its Discretion In Rejecting The Sir Bradford Hill Criteria To establish Scientific Reliability And In Otherwise Finding Dr. Gershwin's Opinion To Be Scientifically Unreliable In This Case; Correspondingly, The Court Of Appeals Committed Reversible Error In Making Its Own Determination That The Bradford Hill Criteria Served As A Substitute For Determining Reliability Absent Independent Data Demonstrating The Requisite Association Between Exposure to Phosphoric Acid And The Onset of WG

In the present case, the trial court properly concluded that not a single article, peer-reviewed study or any other scientific support was produced by Plaintiff to substantiate Dr. Gershwin's novel theory that etching solution or phosphoric acid causes, contributes to, or in any way sparks Wegener's Granulomatosis. (Exhibit A, pp 20-21, 24-29). As such, the trial court held that his theory does not satisfy the burdens imposed by MRE 702 and MCL 600.2955(1) and was, therefore, deemed inadmissible. The trial court's ruling constituted a proper exercise of its discretion. Compare *Elher*, supra.

The trial court noted that throughout his deposition, Dr. Gershwin was asked multiple times whether he is aware of any study, peer-reviewed articles, or other evidence showing a causal connection or even an association between Wegener's and etching solution or phosphoric acid (*Id*., pp 29-30, 31). While he was very argumentative, he ultimately corroborated that no direct scientific support exists, but that "there will be this case" (*Id*., pp 30-31). The court found that Dr. Gershwin exaggerated the findings in some of these articles and that the majority of the articles presented by the parties indicated that the etiology for WG was actually unknown (*id*., pp 21, 25-26, 28).

The trial court also carefully analyzed the epidemiological testing cited by Dr. Gershwin which involved distinguishable environmental factors such as silica, staph aureus bacteria, dust, farming, certain industrial solutions, etc. The trial court acknowledged that some testing involved a claimed connection with pesticides containing phosphates.[1] However, in its discretion, the trial court chose not to give credence to Plaintiff's attempted analogy to phosphates within pesticides and phosphoric acid within the etching solution (*id*., pp 26-27). **Indeed, the record was entirely devoid of any evidence that silica, phosphates, staph bacteria or any other matter identified in the published testing was sufficiently similar to phosphoric acid in order to justify the attempted analogy erroneously advocated by Plaintiff. In this regard, the trial court concluded: [t]he cutting edge of medicine is simply not the standard for a courtroom." (*Id*., p 32).**

As affirmed by the dissenting Court of Appeals Opinion, the trial court also rejected the expert's reliance on the Sir Bradford criteria of causation as a substitution for establishing the scientific reliability of his opinion, particularly where there was nothing in the record to substantiate the threshold requirement of an association between phosphoric acid and WG. (**Exhibit A, pp 22-25**). The trial court relied upon the following holding in *Chapin*, which easily distinguishes *Chapin* from this action*:*

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[1] Contrary to the Court of Appeals ruling, phosphates and phosphorous acid are not the same or sufficiently similar to permit the analogy relied upon by the Court of Appeals:

> Phosphorus is an element that occurs in nature and is widely distributed in combination with other minerals. In your high school chemistry class, it was presented to you as one of the elements on the Periodic Table. Phosphates are natural compounds - salts containing phosphorus and other minerals. The main minerals in bones and teeth are types of phosphates with the scientific names of hydroxyapatite or tricalcium phosphate. Phosphoric acid is produced from phosphates by reacting with sulphuric acid.
>
> Frequently Asked Questions about Phosphate, Phosphorous Acid (PPA), www.phosfatesfacts.org/faqs.asp [See, **Exhibit I**]

> [In Chapin] Both experts agreed that there are two general types of asbestos fibers: shorter serpentine/chrysotile fibers and longer amphibole fibers. Amphibole fibers are significantly more hazardous than chrysotile fibers, but both kinds cause mesothelioma, and the more asbestos one inhales the greater the risk. These facts are not in dispute.
>
> *Chapin*, *supra*, at 130-131(emphasis added)

Consequently, the fact that the inhaled substance in *Chapin*, asbestos, was already accepted by the scientific community, courts, and the federal government as a cause of mesothelioma was undisputed. The only issue was whether the kind or form of asbestos found in brake dust was a possible cause of mesothelioma. There, the Court then allowed expert opinion from a qualified expert to make that connection based on case reports and other "analogous" sources of information. *Id.*

The Court of Appeals original dissenting opinion in this action (reincorporated by reference in Judge Meters dissenting opinion on remand) persuasively distinguished *Chapin* in holding that the Bradford Hill methodology could not serve to scientifically validate the Plaintiff's expert opinion:

> In place of an epidemiological study, plaintiffs primarily rely on the Bradford Hill method to support their theory of causation and to support their argument that Gershwin's testimony was admissible. However, the trial court thoughtfully considered the Bradford Hill method in reaching its conclusions and it carefully distinguished the *Chapin* case. The trial court noted that in Chapin, "the history with asbestos, asbestos causing these problems [i.e., mesothelioma] was clearly well established. . . . [A]sbestos affects all individuals who are exposed to it in essentially the same way." The only dispute in *Chapin* concerned whether brake workers, in particular, would develop mesothelioma as a result of exposure to asbestos-based brake products during their work. See id. at 135. **The present case is fundamentally different because there are evidently no studies showing that phosphoric acid causes WG. Importantly, Gershwin himself admitted that none of the literature he provided showed such causation.** Under the circumstances, I simply cannot find that the trial court abused its discretion by granting defendants' motion in limine
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> **Exhibit D,** J. Meter dissenting, pp 4-5 [emphasis added].

Finally, applying MCL 600.2955(2), the trial court concluded that Dr. Gershwin's opinion and methodology were novel and new, as evidenced by the fact that he wanted to utilize Plaintiff as a case study at the conclusion of this litigation (**Exhibit A, p 20, 27, 32).** Indeed, it was accurately noted that neither Gershwin's opinion or methodology has achieved general scientific acceptance among impartial and disinterested experts in the field . Based upon the trial court's review of the articles cited by the Plaintiffs- and Dr. Gershwin's deposition, the trial court appropriately rejected Dr. Gershwin's expert opinion because it properly concluded that "[h]ere the cause of Wegener's remains mostly a mystery." (Exhibit A, pp 22-23).

Applying the deferential "abuse of discretion" standard of review, the Court of Appeals' review should have been limited to determining whether the trial court's ruling was "outside the range of principled outcomes*."* *Elher, supra; Edry*, supra. **In neither of its vacated original opinion nor on remand did the Court of Appeals majority do so.** As demonstrated by the Court of Appeals' initial dissent (as incorporated into the dissenting opinion on remand), the trial court's ruling was most certainly was within that range**. The trial court fully and accurately applied the standards of Section 2955(1), properly refused to apply the Sir Bradford criteria of causation in place of the section 2955 requirements and arrived at the only conclusion permitted by section 2955(2): rejection of the novel approach of Dr. Gershwin that had not achieved general scientific acceptance.**

Nonetheless, the Court of Appeals majority opinion, while acknowledging the controlling standard of review, simultaneously gave its own detailed analysis as if it was reviewing the issue in the first instance. This approach as a whole was clearly erroneous.

Moreover, there are obvious substantive flaws in the Court of Appeals' majority approach that are palpably erroneous and which compromise the jurisprudence of the State.

First, the Court of Appeals majority erroneously upheld the applicability of the Sir Bradford criteria as a substitute for the controlling statutory analysis and, as a matter of first impression and contrary to all the existing authority, applied that criteria as a proper methodology for determining scientific reliability **even while specifically acknowledging the absence of the threshold existence of data from controlled studies showing an association between phosphoric acid and the onset of WG (see: Exhibit H , pp.13-14).** ***In re Fosamax Prods. Liab. Litigation, supra.*** To requote Judge Meters' original dissenting opinion in this regard:

> The present case is fundamentally different because there are evidently no studies showing that phosphoric acid causes WG. Importantly, Gershwin himself admitted that none of the literature he provided showed such causation.
>
> **Exhibit D**, J. Meter dissenting, pp 4-5.

This blatant error by the Court of Appeals' majority by itself requires Supreme Court relief.

Secondly, and in a similar vein, the Court of Appeals majority erroneously cited to and relied upon the existence of independent studies addressing the association of different and distinguishable chemicals and other environment agents [other than phosphoric acid] as supporting the scientific reliability of Dr. Gershwin's opinion that Plaintiff's exposure to phosphoric acid was a proximate cause of her infliction with WG **(Exhibit H, pp 13-14).** This included, as stated, agents such as phosphates, silica, and staff bacteria. **The deferential "abuse of discretion" standard of review should have limited the majority's analysis to whether the trial court's rejection of plaintiff's proposed analogies to these studies**

involving distinguishable agents was within the range of principled outcomes given the record that was before it. ***Edry, supra***.

However, the Court of Appeals majority went beyond these limitations and permitted the analogies as examples of reliable indicia without any evidence in the trial court record that substantiates identical traits, elements or components between these tested agents and the untested phosphoric acid. This portion of the majority's analysis was also palpably erroneous.

Finally, the Court of Appeals majority erroneously ruled against Defendant without the benefit of an evidentiary hearing requested by the Defendant in the alternative in the trial court for development of further facts.

"[A]n evidentiary hearing under MRE 702 and MCL 600.2955 is merely a *threshold* inquiry to ensure that the trier of fact is not called on to rely in whole or in part on an expert opinion that is only masquerading as science." *Chapin*, supra, 274 Mich App at 139. See also *Clerc v Chippewa Co War Mem Hosp*, 267 Mich App 597; 705 NW2d 703 (2005), [a trial court must not exclude expert testimony under MRE 702 unless it first holds an evidentiary hearing or conducts a "searching inquiry" under MRE 702].

The Court of Appeals' majority analysis contained significant gaps; most particularly, it upheld Dr. Gershwin's analogy to scientific testing conducted upon environmental agents other than phosphoric acids without any testimony supporting that the components of those respective agents are substantially identical. "It is axiomatic in logic and in science that correlation is not causation." *Craig at* 93. The Court of Appeals majority essentially and erroneously permitted a finding of scientific reliability of Dr. Gershwin's testimony linking phosphoric acid exposure to the development of Wegner's Granulomatosis merely because he says it does.

At an absolute minimum, Defendants should be entitled to a remand for a *Daubert* hearing before Dr. Gershwin's unproven theories and analogies may be proffered against it at trial. *Chapin, supra; Clerc, supra*.

CONCLUSION

Defendants-Appellants respectfully request this Honorable Court grant leave to appeal or peremptorily vacate the Court of Appeals opinion and affirm the order of the Eaton County Circuit Court striking Dr. Gershwin's testimony from consideration in this case.

Respectfully submitted,

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By: **/s/ Keith P. Felty**

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INDEX OF EXHIBITS